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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/573,363	03/24/2006	Tesfaye Biftu	21587P	2722

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EXAMINER	
RAO, DEEPAK R	

ART UNIT	PAPER NUMBER
1624	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/573,363	BIFTU ET AL.	
	Examiner	Art Unit	
	Deepak Rao	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20060324*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-55 are pending in this application.

Specification

The disclosure is objected to because of the following informalities:

1. In page 22, in Scheme I, right side of the page there is incomplete structure and text.
2. In page 30, it is disclosed that Example 5 is a compound 2-(4-Fluorophenyl)-7-(1-methylpiperidin-4-yl)-3-**(pyrimidin-4-yl)**imidazo[1,2-a]pyridine. The structural formula, however, shows a **pyridin-4-yl** group. The reaction steps on the following pages describe the preparation of the compound having a **pyrimidin-4-yl** group. There is inconsistency between the structure and the process steps.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 28-55 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition comprising the compound of formula (I); and a method

for the treatment of coccidiosis, does not reasonably provide enablement for a composition comprising a second anticoccidial agent; or a method for controlling coccidiosis with **prophylactically** effective amount of the compound of formula (I); or a method for controlling malaria, African trypanosomiasis, Chagas disease, or toxoplasmosis with **prophylactically** effective amount of fomrula (I). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In evaluating the enablement question, several factors are to be considered. Note *In re Wands*, 8 USPQ2d 1400 and *Ex parte Forman*, 230 USPQ 546. The factors include: 1) The nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or absence of working examples, 6) the breadth of the claims, and 7) the quantity of experimentation needed. The determination that "undue experimentation" would have been needed to make and use the claimed invention is not a single, simple factual determination. Rather, it is a conclusion reached by weighing all the above noted factual considerations.

The instant claims 32-44 are is drawn to 'a composition for controlling coccidiosis, malaria, etc.'. When a compound or composition claim is limited by a particular use, enablement of that claim should be evaluated based on that limitation. See MPEP § 2164.01(c). In contrast, when a compound or composition claim is **not** limited by a recited use, any enabled use that would reasonably correlate with the entire scope of that claim is sufficient to preclude a rejection for non-enablement based on how to use.

The instant method claims are drawn to 'a method for controlling coccidiosis, malaria, African trypanosomiasis, Chagas disease, or toxoplasmosis with **prophylactically** effective amount of formula (I)' and the specification discloses that the compounds have anticoccidiosis properties useful to treat a variety of parasitic diseases. Test assays and procedures are provided in the specification in page 20 related to evaluating anticoccidial activity of the compounds, and it is concluded that the compounds of the invention are useful for antiparasitic treatment, however, there is nothing in the disclosure regarding how this test data correlates to the treatment of the diverse disorders encompassed by the instant claims. Further, there is no reasonable basis for assuming that the myriad of compounds embraced by the claims will all share the same physiological properties since they are so structurally dissimilar as to be chemically non-equivalent and there is no basis in the prior art for assuming the same. Note *In re Surrey*, 151 USPQ 724 regarding sufficiency of disclosure for a Markush group.

It is inconceivable as to how the claimed compounds can treat the entire class of parasitic diseases embraced by the claims having diverse mechanisms, involving various organisms and numerous strains thereof. See http://www.aber.ac.uk/~mpgwww/Edu/ParProto/ProtoTxt.html which reports that 'there are over 50,000 species of protozoa, of which ha fifth are parasitic' and that 'there is great variability between different strains'. Regarding *Coccidia* the article provides that "The number of different species of coccidian is staggering..... the vast majority of Coccidia species are probably yet to be described". In reference to 'parasitic diseases', The Merck Veterinary Manual provides that 'clinical experience with many of the diseases is limited' (see http://www.merckvetmanual.com/mvm/index.jsp?cfile=htm/bc/170709.htm). The instant claim language encompasses all types of parasitic disorders occurring in animals including human in

general. There is no evidence of record which would enable the skilled artisan in the identification of the animal which has the potential of becoming afflicted with the disease(s) or disorder(s) claimed herein and therefore, require the treatment. Applicants have not provided any competent evidence or disclosed tests that are highly predictive for the pharmaceutical use of the instant compounds. Pharmacological activity in general is a very unpredictable area. Note that in cases involving physiological activity such as the instant case, "the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved". See *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). For example, the state of the art regarding a common skin disorder that occurs in dogs, it is expressed that "Generalized demodicosis is serious and often difficult to treat" (see http://pethealthclinic.tripod.com/skin/). Therefore, the state of the art provides the need of undue experimentation for the instantly claimed therapeutic benefits.

Furthermore, the scope of the claims is not adequately enabled solely based on anticoccidiosis activity provided in the specification. The instant claims are drawn to 'a method of controlling … using **prophylactically** effective amount of the compound...' of parasitic diseases, and therefore, the instant claim language embraces disorders not only for the treatment, but for "**prevention**" which is not remotely enabled. The instant compounds are disclosed have 11B-HSD1 inhibitory activity and it is recited that the instant compounds are useful in the "prevention" of parasitic diseases, for which applicants provide no competent evidence. "To prevent" actually means *to anticipate* or *counter in advance, to keep from happening etc.* (as per Websters II Dictionary) and therefore it is not understood how one skilled in the art can reasonably establish the basis and the type of subject to which the instant compounds can be

administered in order to have the "prevention" effect. The specification provides assay for anticoccidiosis activity, which relates to coccidiosis mechanism. Thus, it is inconceivable as to how the claimed compounds can not only treat but also "prevent" all diseases of the instant claims. There is no evidence of record, which would enable the skilled artisan in the identification of the people who have the potential of becoming afflicted with the disease(s) or disorder(s) claimed herein.

(Only a few of the diseases embraced by the instant claims are discussed here to make the point of an insufficient disclosure, it does not definitely mean that the other diseases meet the enablement requirements).

Thus, factors such as "sufficient working examples", "the level of skill in the art" and "predictability", etc. have been demonstrated to be sufficiently lacking in the use of the invention. In view of the breadth of the claim, the chemical nature of the invention, and the lack of working examples regarding the activity of the claimed compounds, one having ordinary skill in the art would have to undergo an undue amount of experimentation to use the invention commensurate in scope with the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-26 and 28-55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

1. In claim 1, in the recitation: " or a pharmaceutically acceptable salt, or N-oxide, thereof ", there is an extra 'comma' (,) following the term 'N-oxide' which is confusing.
2. Claim 21 is drawn to a compound of formula (II) which is of different scope than that of the structural formula (I) of claim 1, however, claim 21 is dependent on claim 1 - this is not proper. Claim 21 is broader than claim 1 and therefore, should not depend from claim 1.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ormum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 21 and 52-55 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-44 of copending Application No. 10/548,154. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims substantially overlap the reference claims. The reference claims are drawn to a generic group of compounds and the instantly

claimed genus overlaps the genus of the reference claims. It would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the species of the genus taught by the reference, including those instantly claimed, for example, an ester, because the skilled chemist would have had the reasonable expectation that any of the species of the genus would have similar properties and, thus, the same use as taught for the genus as a whole i.e., as pharmaceutical agents. One of ordinary skill in the art would have been motivated to select the claimed compounds from the genus in the reference since such compounds would have been suggested by the reference as a whole.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Duplicate Claims

Applicant is advised that should claim 32 be found allowable, claims 44, 46, 48 and 51 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Claims 44, 46, 48 and 51 are drawn to a composition comprising a compound of formula (I) and the claims recite an intended use for the composition.

Allowable Subject Matter

Claim 27 is allowed. The closest reference of record, U.S. Patent No. 6,596,731 does not teach or fairly suggest the instant compounds.

Receipt is acknowledged of the Information Disclosure Statement filed on March 24, 2006 and a copy is enclosed herewith. (The typographical error of the Patent document number in PTO-1449 was corrected).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (571) 272-0672. The examiner can normally be reached on Monday-Friday from 8:00am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Deepak Rao/
Primary Examiner
Art Unit 1624

January 8, 2008